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25481-P001US



PATENT  
APPLICATION NO. 09/902,176

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Stefan Schreiber et al.

Serial No.: 09/902,176

Filing Date: July 10, 2001

Confirmation No: 7507

Art Unit: 1634

Examiner: Sally A. Sakelaris

Title: DIAGNOSTIC USE OF POLYMORPHISMS IN THE GENE CODING FOR THE TNF  
RECEPTOR II AND METHODS FOR DETECTING NON-RESPONDERS TO  
ANTI-TNF THERAPY

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to the provisions of 37 CFR §§ 1.56, 1.97 and 1.98, and MPEP 609, Applicant submits herewith copies of the documents listed on the attached Form SB/08B "Information Disclosure Statement by Applicant."

**REMARKS**

Consideration by the Examiner of each of the documents listed on Form SB/08B is respectfully requested. Applicant respectfully requests that a copy of SB/08B, as considered and initialed by the Examiner, be returned to the undersigned with the next Official Communication.

The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. 37 CFR § 1.97(g). Furthermore, the filing of this

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Information Disclosure Statement shall not be construed to be an admission that the information cited in this Statement is, or is considered to be, prior art, analogous art, or material to patentability of this application, but the information has been cited to make it clear beyond all doubt that Applicant's duty of disclosure has been complied with. 37 CFR § 1.97(h).

Applicant hereby submits that the claims of Applicant's above-referenced patent application are patentably distinguishable from these references.

It is believed that no fees are due; however, the Director is hereby authorized to charge any fees relating to this Information Disclosure Statement under 37 CFR § 1.17 to Deposit Account No 23-2426 of WINSTEAD SECHREST & MINICK P.C.

Respectfully submitted,

Date: December 14, 2004

Melissa D. Schwaller  
Melissa D. Schwaller  
Registration No. 46,089

WINSTEAD SECHREST & MINICK P.C.  
P.O. Box 50784  
Dallas, Texas 75201  
Telephone: 214.745.5633  
Facsimile: 214.745.5390

ATTORNEYS FOR APPLICANT



PTO/SB/08B (04-03)

Approved for use through 04/30/2003. OMB 0651-0031  
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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**Complete if Known**

|                        |                    |
|------------------------|--------------------|
| Application Number     | 09/902,176         |
| Filing Date            | July 10, 2001      |
| First Named Inventor   | Stefan Schreiber   |
| Art Unit               | 1634               |
| Examiner Name          | Sally A. Sakelaris |
| Attorney Docket Number | 25481-P001US       |

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**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.                       | T <sup>2</sup> |
|--------------------|-----------------------|---|----------------|
|                    |                       | FABRIS, et al.; Tumor necrosis factor-alpha receptor II polymorphism in patients from southern Europe with mild-moderate and severe rheumatoid arthritis; Journal of Rheumatology; 2002 Sep; 29(9); 1847-50.  |                |
|                    |                       | OGILVIE, et al.; Treatment of psoriatic arthritis with antitumour necrosis factor-alpha antibody clears skin lesions of psoriasis resistant to treatment with methotrexate; Br. J. Dermatol.; 2001 Mar; 144(3):587-9.   |                |
|                    |                       | YEE AND POCHAPIN; Treatment of complicated sarcoidosis with infliximab anti-tumor necrosis factor-alpha therapy; Ann Intern Med. 2001 Jul 3; 135(1):27-31.  |                |
|                    |                       | ARINGER, et al; Safety and efficacy of tumor necrosis factor alpha blockade in systemic lupus erythematosus: an open-label study; Arthritis Rheum. 2004 Oct; 50(10):3161-9.   |                |
|                    |                       | BECKER, et al; TGF-Beta suppresses tumor progression in colon cancer by inhibition of IL-6 trans-signaling; Immunity, Vol 21, 491-501; October 2004, Cell Press.  |                |
|                    |                       | ROSE-JOHN AND NEURATH, et al.; IL-6 trans-signaling: The heat is on; Immunity; Vol 20, 1-20, January 2004, Cell Press.  |                |
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|                    |                       | CHOY, et al.; Efficacy of a novel PEGylated humanized anti-TNF fragment (CDP870) in patients with rheumatoid arthritis: a phase II double-blinded, randomized, dose-escalating trial; Rheumatology 2002; 41:1133-1137; British Society for Rheumatology.                              |                |

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|--------------------|--|-----------------|--|
| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

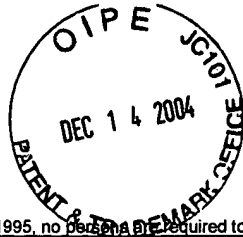
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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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|--------------------|-----------------------|---|----------------|
|                    |                       | SANDBORN, et al; An Engineered Human Antibody to TNF (CDP571) for Active Crohn's Disease: A Randomized Double-Blind Placebo-Controlled Trial; Gastroenterology 2001; 120:1330-1338; American Gastroenterological Association.                                   |                |
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|                    |                       | ELLIOTT, et al.; Repeated therapy with monoclonal antibody to tumour necrosis factor alpha (cA2) in patients with rheumatoid arthritis; Lancet, October 22, 1994; 344(8930):1125-7  |                |
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Examiner  
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